United States Senate
WASHINGTON, DC 20510

April 30, 2014

The Honorable Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

As the FDA works on the Action Plan required by Section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA), we are writing to urge that this plan recommend clear and actionable strategies to improve the representation of women and minorities in clinical research, ensure that meaningful subgroup analyses are conducted, and make subgroup-specific clinical trial results publicly available and accessible. We are strong supporters of this provision and view the Action Plan as a critical opportunity to provide women and minorities with confidence that prescription drugs and medical devices are safe and effective for their use.

Although two decades have passed since FDA published its guideline requiring analysis of data on sex differences in the evaluation of new drugs, we remain concerned about recent evidence that women still are not being adequately represented in clinical trials. As a result, medical treatments may not be as safe and effective for women as they may expect. A February *60 Minutes* story highlighted the recent example of the drug Ambien, which metabolizes differently in women and men – meaning that women have been unsuspectingly receiving an inappropriately high dose of the drug for years.

A March report by researchers at the Brigham and Women's Hospital, entitled, "Sex-Specific Medical Research: Why Women's Health Can't Wait," underscores how women are disproportionately affected by diseases such as lung cancer, heart disease, Alzheimer's, and depression, even while the medical treatments available to them were tested largely in men. Finally, the FDA's own August 2013 report required by FDASIA showed that, while progress has been made, gaps still remain in the full representation of women in clinical trials, analysis of the safety and effectiveness data by sex, and making information about treatment differences readily available to women and their healthcare providers.

The Action Plan represents a key opportunity to address these concerns. We hope that, 20 years from now, we can look back and say that the FDA's plan was a significant milestone in women's health – not a missed opportunity. We encourage the FDA to incorporate the following recommendations into the Action Plan:

- Require that representative proportions of women and minorities be included in industry-sponsored clinical trials comparable to what NIH required two decades ago.

- Spell out the specific actions that FDA will take, in cooperation with industry stakeholders, in order to achieve meaningful subgroup-specific analyses for safety and efficacy, along with clear timelines for enforcement while ensuring that clinical trials are not unnecessarily disrupted and making the results transparent and publicly available.
- Put in place a process for tracking and publicly reporting on the progress in implementing the Action Plan on a regular basis and for taking further action as needed to achieve equitable representation.

Thank you for your consideration of our comments. We want to be as helpful as possible in working with you to produce an aggressive Action Plan that furthers our goal of better understanding how disease and treatments for disease affect women and minorities differently.

Sincerely,

Jenny Baldini

Kirsten Gillibrand

Jane Manchester